UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL CAUSATION MEDICAL EXPERTS

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INTRODUCTION

In their Opposition, Plaintiffs do not seriously dispute that the general causation opinions of their three medical causation experts – Dr. Samet, Dr. Jarvis, and Dr. Stonnington ("SJS") – depend on their extrapolation from the "association" found in the McGovern study. SJS admitted that they could not have reached their opinions that the Bair Hugger causes surgical site infections without the "puzzle piece" of the McGovern study, because it is the only study that purports to find an "association" between Bair Hugger use and SSIs in the real world.[1] There likewise is no dispute that SJS rely on the McGovern study *alone* to quantify the purported increased risk and for their opinion that, in all surgical site infection cases, the Bair Hugger system will be a substantial contributing cause. Without the McGovern study, SJS could not say whether the Bair Hugger system is in any case a "substantial" contributing cause or an insubstantial one.

Defendants' opening brief demonstrates that the McGovern study is far too weak to support causation and is also fatally flawed. It suffers from tabulation errors (errors that likely occurred while the underlying data were in the custody of Augustine employee Mark

[1] DX3, Samet Dep. at 282:16-23 ("The McGovern paper supplies the only estimate of the risk associated for deep joint infection associated with use of the forced-air warming Bair Hugger device. So absent the quantitative estimate from that paper, it would be – while there would be a quite plausible mechanistic basis for increased risk, there would not been asked [sic] an association in – in the real world."); DX5, Jarvis Dep. at 190:15-19 ("Q. Was there any other study that you referenced in your report that purported to show a relative risk of Bair Hugger versus some other warming modality in terms of joint infections? A. No. That was – that was the solid one."). Stonnington somewhat confusingly testified that "[i]f McGovern didn't exist I would still be sitting here today," DX26, Stonnington Dep. at 118:19-119:11, but moments later acknowledged that "you have to put [McGovern and other studies] all together to make a conclusive argument," *id.* at 121:25-122:10.

Albrecht) that, when corrected, vitiate the statistical significance of the purported "association." The "association" also disappears when one accounts for confounding factors and bias, as an expert must do under both reliable epidemiological practice and case law. *See, e.g., In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1043 (D. Minn. 2007) (Davis, J.) ("It is generally accepted that bias in the conduct of a study can materially affect the result and that detection and accounting for bias are standard tools of epidemiology."). When one controls for just the confounders disclosed by the McGovern authors, as Defendants' expert Prof. Holford did (and indeed study author Albrecht conceded at his deposition), the "association" between the Bair Hugger system and surgical site infections also disappears. Add to this that the hospital studied by the McGovern authors implemented a massive infection control initiative that primarily benefited the non-Bair Hugger patients. Add further the fact that the study authors selected a start date for their data set that achieved (barely) statistical significance. If they had chosen any earlier start date or nearly any later start date, as they had originally planned to do, they would not have achieved statistical significance. While statistical significance is not necessarily the "Holy Grail" of admissibility,[2] lack of statistical significance is an important factor for the Court to consider in determining what inferences can be drawn from a study. *See In re Prempro Prods. Liab. Litig.*, 738 F. Supp. 2d 887, 891 (E.D. Ark. 2010) (Montgomery, J.). Whether these flaws are considered individually or together, McGovern plainly is not reliable, nor

[2] *But see Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 461 (W.D. Pa. 2003) ("Courts have emphasized that epidemiologic proof must be statistically significant.")

is it "scientifically convincing evidence" of causation. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989-90 (8th Cir. 2001).

The arguments in Plaintiffs' Opposition boil down to four points. They argue, first, that the law does not require their experts to "look behind the curtain" of the McGovern study to assess its internal validity; experts may rely on even a flawed study, like McGovern, if peer reviewed and published. Second, Plaintiffs argue that even if Defendants' experts are right about the law, the McGovern study's flaws are not substantial enough to render it unreliable. Third, they argue that SJS have applied the same rigor to their litigation opinions that they apply in their professional capacities. Fourth, Plaintiffs argue that the independent authorities, such as the FDA, who have rejected Plaintiffs' experts' theory of causation are irrelevant to the admissibility of their testimony.

Plaintiffs are wrong on each point.

First, the Eighth Circuit's *Glastetter* decision requires that general causation opinions be based upon scientifically convincing evidence. *Glastetter* echoes *Daubert's* requirement that "[i]n a case involving scientific evidence, *evidentiary reliability* will be based upon ***scientific validity***." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 n.9 (1993) (bold emphasis added). With this comes the requirement that an expert thoroughly evlauate the internal validity of the key study or studies upon which the expert relies – particularly where, as here, a study is based on an inherently suspect format and exhibits numerous "danger signals" suggesting that it may suffer from confounding and bias. *See Turpin v. Merrell Dow Pharms, Inc.*, 959 F.2d 1349, 1352-53 (6th Cir. 1992).

Contrary to Plaintiffs' unsupported assertion, there is no "landslide" of case authority to the contrary.

Second, this is not merely an "all studies have flaws" situation. The McGovern study states clearly that "[t]his study does not establish a causal basis for this association." DX11, McGovern at 1543.[3] Moreover, the McGovern study suffers from data manipulation, multiple confounders (including confounders disclosed in the study itself), and bias that vitiate its reliability. It is precisely these types of defects in the data underlying an epidemiological study that led the Viagra MDL court to exclude the plaintiffs' general causation expert and grant summary judgment for the defendants. The court initially denied the defendants' motion to exclude the plaintiffs' general causation experts because they relied upon a peer-reviewed, published study. But following additional discovery that exposed data discrepancies, it revisited that decision and granted the defendants' renewed motion. *See In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 944-45, 950 (D. Minn. 2009) (Magnuson, J.) ("*Viagra II*").[4] Plaintiffs here do not and cannot cite any case, much less from the Eighth Circuit, that has ever concluded that a study that suffers from such pervasive flaws can reasonably be relied upon by general causation experts. Certainly, the McGovern study cannot bear the weight that SJS put on

[3] References to "DX" are to the exhibits to the Declaration of Benjamin W. Hulse in Support of Defendants' Motion to Exclude Plaintiffs' General Causation Medical Experts (ECF No. 751) or to the Second Declaration of Benjamin W. Hulse, filed concurrently with this Reply.

[4] Throughout their briefing, Plaintiffs have repeatedly and inexplicably cited Judge Magnuson's first *Viagra* decision, where he initially denied the defendants' *Daubert* motion, rather than the second *Viagra* decision, where he excluded the plaintiffs' general causation expert after the defendants exposed flaws in the data underlying a key study.

it here, as the sole support for their contention that the Bair Hugger system causes surgical site infections in the real world.

Third, Plaintiffs do not and cannot identify any time in SJS's professional or litigation careers where they have formed a causation opinion based upon such weak support. As Dr. Samet explains in his own report, inferences of causation from observational studies are made based on consistent results across multiple studies. DX2, Samet Rpt. at 16. When an expert sees the same association across multiple studies, it is far less likely that the association is the product of confounding, bias, or data errors. Yet here Dr. Samet and his fellow medical experts make the flying leap to their causation opinion based on a single weak and flawed observational study – a study that disclaims any finding of causation and suffers from disclosed but uncontrolled confounders. SJS's willingness to take peer-reviewed, published literature at face value, despite numerous danger signals, and make unjustified extrapolations is further demonstrated by their rush to embrace a recently published observational "study" by Dr. Scott Augustine. (*E.g.*, DX25, Samet Dep. at 30:4-23.) Plaintiffs now try to repudiate that "study" as it emerged it was premised on misrepresenting data.

Fourth, both federal law and Minnesota law consider whether experts' *theories* – not just their methodologies – are generally accepted. *See* Fed. R. Evid. 702 Adv. Comm. Notes (2000) (nonexclusive *Daubert* factors include "whether the technique or ***theory*** has been generally accepted in the scientific community"); Minn. R. Evid. 702 ("[I]f the opinion or evidence involves novel scientific ***theory***, the proponent must establish that the underlying scientific evidence is generally accepted in the relevant scientific community.")

(Emphasis added)). Indeed, general acceptance is requirement of Minnesota law. SJS's novel theory that the Bair Hugger system causes surgical site infections is not generally accepted, and in fact has consistently been rejected by independent authorities, including most recently the FDA.

For all these reasons, as well as the reasons discussed below and in Defendants' opening brief, the testimony and opinions of SJS should be excluded under *Daubert*, Fed. R. Evid. 702, and Minn. R. Evid. 702.

ARGUMENT

I. EIGHTH CIRCUIT LAW REQUIRES THAT EXPERT OPINIONS BE BASED ON VALID SCIENTIFIC EVIDENCE.

A. The Requirement of Scientifically Convincing Evidence to Support a General Causation Expert's Opinion Is Consistent with *Daubert.*

Glastetter is the controlling case in the Eighth Circuit on how a district court should go about evaluating expert testimony on general causation. *See Glastetter*, 252 F.3d at 989-90. It provides the standard by which Plaintiffs' general causation experts must be judged.[5] In *Glastetter*, the Eighth Circuit affirmed the district court's exclusion of the plaintiffs' general causation experts, concurring with the district court that the medical texts, animal studies, case studies, dechallenge/rechallenge data, and corporate documents upon which

[5] Plaintiffs dismiss *Glastetter* as an "unsigned per curiam" opinion with no legal effect. Opp. at 6. Plaintiffs may be confusing per curiam opinions with unpublished opinions, because a per curiam opinion is no less binding than any other published opinion in the Eighth Circuit. Unsurprisingly, *Glastetter* has been cited 15 times by the Eighth Circuit, most recently in *Adams v. Toyota Mot. Corp*., 867 F.3d 903, 916 (8th Cir. 2017), and has been cited 22 times by courts in the District of Minnesota. Plaintiffs may not like *Glastetter*, but if they want Eighth Circuit law changed, they will need to convince the Eighth Circuit *en banc* or the U.S. Supreme Court.

those experts relied were not "scientifically convincing evidence" of general causation. The requirement that an expert's opinion be based on scientifically valid evidence leads, in this case, to the requirement that both experts and the gatekeeping court "look behind the curtain," and assess the validity of the studies on which the experts rely – including those, like the McGovern study, that are peer reviewed.

Plaintiffs dismiss *Glastetter*'s use of the phrase "scientifically convincing evidence" as a dictum and assert that it is inconsistent with other Eighth Circuit law and *Daubert*. Opp. at 7. But the Eighth Circuit repeated this same language just a few years ago in *Mead Johnson*, a decision that addressed specific causation expert opinions. Summarizing *Glastetter*, the Eighth Circuit stated:

> In *Glastetter*, the plaintiff sought to admit expert testimony that the drug Parlodel, which she took to suppress lactation after giving birth, can cause intracerebral hemorrhages (stroke). The expert used a differential diagnosis, which we found was, generally speaking, a reliable method under *Daubert*. However, the expert in *Glastetter* opined that Parlodel might cause strokes because Parlodel likely caused arteries to constrict, and vasoconstriction is a known cause of strokes. The problem with this testimony was that the experts had no scientific proof that Parlodel caused vasoconstriction.
>
> As we noted, "its major premise remains unproven" because there was no "***scientifically convincing evidence*** that Parlodel causes vasoconstriction." Although the experts attempted to present such evidence in the form of case reports and medical texts, we found these sources to be unreliable.

Johnson v. Mead Johnson & Co., LLC, 754 F.3d 557, 563 (8th Cir. 2014) (emphasis added).

Glastetter's requirement of "scientifically convincing evidence" is also entirely consistent with Supreme Court precedent. As *Glastetter*'s citations make clear, the Eighth

Circuit was paraphrasing the Supreme Court's statement in *Daubert* that "[i]n a case involving scientific evidence, evidentiary reliability will be based upon ***scientific validity***." *Glastetter*, 252 F.3d at 989 (quoting *Daubert*, 509 U.S. at 590 n.9 (bold emphasis added)). Plainly, "scientifically valid" evidence will also be "scientifically convincing." Indeed, *Glastetter* is consistent with the fundamental thrust of *Daubert*: even highly qualified experts may not rely on or promote flawed science. Nor may experts make flying leaps beyond the conclusions of the existing science, based only upon their qualifications and "experience."

B. Plaintiffs Are Incorrect That There Is a "Landslide" of Cases Contrary to *Glastetter*.

On this point, Plaintiffs also deny that *Glastetter* stands for the rule that an expert cannot draw conclusions that go beyond those of the authors of the medical texts on which they rely. Opp. at 7. But that is precisely what the Eighth Circuit held. In *Glastetter*'s discussion of the medical texts upon which the plaintiff's general causation experts relied, the Eighth Circuit noted that the farthest any text went was to "venture[ ] a hesitant conclusion that Parlodel [the drug sold by the defendant] causes vasoconstriction," a precursor to intracerebral hemorrhages, but "the explanation made clear that more research was needed before causation could be firmly established." 252 F.3d at 990. The Eighth Circuit concurred with the district court's finding that this text "do[es] not present persuasive scientific evidence that Parlodel causes vasoconstriction." *Id.*

The "hesitant" conclusion on causation in the medical text in *Glastetter* is far stronger than McGovern's finding of "association" and the other studies relied on by Plaintiffs' medical experts. All those studies expressly *disclaim* any finding of causation.[6]

Plaintiffs also argue that there is a "landslide" of cases contrary to *Glastetter*. Opp. at 14. *Glastetter* is, of course, controlling and there is no contrary subsequent Eighth Circuit decision. *Glastetter*'s rule also has been adopted directly or affirmed on appeal by appellate courts across the country.[7] The rule is further supported by *General Elec. Co. v.*

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[6] The Augustine-orchestrated "mechanistic" studies upon which SJS and Plaintiffs' engineering experts rely are addressed in the briefing on Defendants' Motion to Exclude the Opinions and Testimony of Plaintiffs' Engineering Experts Daniel Koenigshofer, Michael Buck, Said Elghobashi, and Yadin David.

[7] *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 137 F. Supp. 2d 147, 187-88 (E.D.N.Y. 2001) (noting that "[g]iven that Means et al. declined to attribute the [peripheral nervous system] effects they observed to xylene simply because it was the most prevalent solvent in the lacquer, it is highly questionable how Dr. Rutchkic can reliably conclude from their work that xylene can cause [polyneuropathy]," and excluding expert's testimony), *aff'd in relevant par*t, 303 F.3d 256, 270 (2d Cir. 2002); *Huss v. Gayden*, 571 F.3d 442, 458-59 (5th Cir. 2009); *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 826 (7th Cir. 2010) ("To the extent that Dr. Hirsch does rely on medical literature to support his [causation] theory, the articles to which he cites stop short of reaching the same conclusion."); *Newkirk v. ConAgra Foods, Inc.*, 727 F. Supp. 2d 1006, 1027-29 (E.D. Wash. 2010) (excluding plaintiff's expert who drew conclusion that the authors of the study on which he relied "explicitly stated was premature without additional data"), *aff'd*, 438 F. App'x 607 (9th Cir. 2011); *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1337-38 (11th Cir. 2010) ("More importantly, the study did not reach a conclusion as to the general causation of chondrolysis, stating that '[n]o etiology [of chondrolysis] has been firmly identified . . .' and that further research was needed. All that the authors were able to state was that pain pumps eluting Marcaine 'appear highly associated with post-arthroscopic glenohumeral chondrolysis.'"). *Similarly, see Perry v. Novartis Pharm. Corp*, 564 F. Supp. 2d 452, 468 (E.D. Pa.2008) ("[N]on-existence of good data does not allow expert witnesses to speculate or base their conclusions on inadequate supporting science. In cases where no adequate study shows the link between a substance and a disease, expert testimony will generally be inadmissible, even if there are hints in the data that some link might exist.").

Joiner, 522 U.S. 136, 146 (1997). In *Joiner*, a toxic tort case, the Supreme Court found no abuse of discretion where "[t]he District Court . . . concluded that the . . . epidemiological studies upon which [the plaintiff's general causation experts] relied were not a sufficient basis for the experts' opinions." *Id.* at 145-46. While "[t]rained experts commonly extrapolate from existing data[,] nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."[8] *Id.* at 146.

Plaintiffs' "landslide" of purportedly contrary authority includes the dissent in *Huss*; an Oregon district court case that precedes the Ninth Circuit's affirmance of *Newkirk* (see footnote 7, *supra*) and a California district court case that relies on the Oregon case; a footnote in a Court of Federal Claims case; and the Grande Ronde Tribal Court. Opp. at 14 & n.1. This is barely a handful of pebbles, much less a landslide. Certainly, none of it is controlling. And none of it justifies SJS's magical transmutation of studies that ***disclaim*** any finding of causation into studies that purportedly support causation to an "acceptable degree of medical certainty." *Glastetter*, 252 F.3d at 989.

[8] The rule is also supported by several of the nonexclusive criteria listed in the 2000 Advisory Committee Notes to Rule 702, including "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion," "[w]hether the expert has adequately accounted for obvious alternative explanations," and "whether the . . . theory has been generally accepted in the scientific community."

C. The McGovern Study Is Not *Per Se* Reliable Merely Because It Is Published and Peer Reviewed.

Next, Plaintiffs argue (as they have done repeatedly in their briefs) that studies like McGovern that are peer reviewed and published are *per se* reliable. According to Plaintiffs, Plaintiffs' medical experts were not required – even when the scientific validity of the studies upon which they relied were called into serious question – to analyze the underlying data to confirm that it supported the studies' conclusions, or to exclude other possible explanations for the reported results. This was SJS's position as well. DX25, Samet Dep. at 45:11-19 ("Well, I – the McGovern study was published in the peer reviewed literature. Again, reanalysis of the raw data is not necessarily a requisite standard for validity.").

Plaintiffs and SJS could not be more wrong. In *Daubert*, the Supreme Court noted that peer review was "not dispositive" of a publication's "scientific validity." 509 U.S. at 594. In *Kumho Tire*, the Court held that when an expert's "factual basis [or] data" are "called sufficiently into question," the "trial judge must determine whether the testimony has a reliable basis in the knowledge and experience of the relevant discipline." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999) (internal quotation omitted). Accordingly, when there is reason the question the validity or the analysis of the data underlying a key study, district courts must "look behind the curtain" instead of simply relying on the fact that the study is peer reviewed and published. *See Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 355 (5th Cir. 2007) ("District courts must carefully analyze the studies on which experts rely for their opinions before admitting their testimony.").

That is what Judge Magnuson did in the Viagra MDL, excluding the plaintiffs' general causation expert who relied on a peer-reviewed study that was shown, following discovery of the underlying data, to suffer from major flaws. *See Viagra II*, 658 F. Supp. 2d at 950. Likewise, in the Baycol MDL, Judge Davis excluded the plaintiffs' general causation medical expert's opinion because there were "inherent uncertainties in the numerator and denominator used" in the data underlying the epidemiological study he reanalyzed. *Baycol*, 532 F. Supp. 2d at 1043-44.

There are many other examples of courts outside this District evaluating whether the data underlying a key study do, in fact, support the study's conclusions. Famously, Andrew Wakefield published an article in *The Lancet* in 1998 finding that the measles-mumps-rubella (MMR) vaccine was associated with autism. Ultimately, *The Lancet* retracted the article due, in part, to Wakefield manipulating his raw data to tell a plaintiff-friendly story. DX30, Editors of the Lancet, "Retraction – Ileal-lymphoidnodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children," 375 *Lancet* 445 (2010). However, ***even prior to retraction***, serious questions about the underlying data led the U.S. Court of Federal Claims to disregard the testimony of experts who relied on the "peer-reviewed" article. *See Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *79, 109-11 (Fed. Cl. Feb. 12, 2009).

Similarly, a New Jersey court excluded an expert relying on his own peer-reviewed article for several flaws made evident by the revelation of the study's raw data – or lack thereof. *See Palazzolo v. Hoffman La Roche, Inc.*, 2010 WL 363834 (N.J. Super. Ct. App. Div. 2010). In that case, the expert had published a peer-reviewed article associating

Accutane with depression. *Id.* at *1. After the defendants had a chance to review the study's underlying data, the expert "was repeatedly confronted with problems in the . . . study, including missing data, inaccurate data, and deviations from the methodology he claimed to have followed." *Id.* at *2. The trial court therefore excluded the study, and an appellate court affirmed. *Id.* at *4-5 ("An expert's scientific peers cannot fairly judge the expert's written work, including whether it is worthy of publication, if his article does not accurately represent either the underlying data or what the author did to produce his results.").[9]

The Sixth Circuit's response to an identical argument by the plaintiff in *Turpin* is highly instructive. There, the court noted that there may be a "combination of danger signals" associated with an expert's testimony that requires the court to scrutinize the evidence more closely:

> We believe that close judicial analysis of such technical and specialized matter is necessary not only because of the likelihood of juror misunderstanding, but also because expert witnesses are not necessarily always unbiased scientists. They are paid by one side for their testimony.

[9] The case upon which Plaintiffs heavily rely, *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230 (W.D. Wa. 2003), further underscores the importance of evaluating the data underlying key studies. While observing that scientific studies almost invariably contain flaws, the court concluded that, "[w]hen faced with epidemiological evidence, the court must determine whether the flaws compromise the study's findings." *Id.* at 1240 (emphasis added). The court then conducted a "close examination of the arguments and supporting evidence" and found that the HSP's "flaws," including any flaws unknown to the FDA and/or the *New England Journal of Medicine*, were either "inaccurately identified [by the defendants] as flaws or inconsequential to the reliability of the study as a whole." *Id.* This "close examination" is exactly what Plaintiffs' medical experts should have done here, and what the Court must do in evaluating the reliability of the McGovern study.

> Although there is no suggestion of unethical scientific conduct in the present case, the potential for exaggeration and fraud on the court is present and may be impossible to discover without close inspection and careful consideration of the record. As Judge Leventhal observed in the context of administrative law, in some circumstances there exists a "combination of danger signals" requiring enhanced "judicial vigilance to enforce the Rule of Law." *Greater Boston Television Corp. v. F.C.C.*, 444 F.2d 841, 851-52 (D.C. Cir. 1970).
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> In such situations, "a court does not depart from its proper function when it undertakes a study of the record, hopefully perceptive, even as to evidence on technical and specialized matters . . . ." *Id.* at 850.

Turpin, 959 F.2d at 1352-53. While *Turpin* is pre-*Daubert*, it was cited with approval by the Supreme Court in *Daubert*, 509 U.S. at 596, and *Joiner*, 522 U.S. at 146.

II. THE MCGOVERN STUDY IS NOT SCIENTIFICALLY VALID EVIDENCE OF GENERAL CAUSATION.

A. McGovern Exhibits a "Combination of Danger Signals" That Requires Scrutiny of Its Findings and the Underlying Data.

The McGovern study exhibits many danger signals on its face. Those danger signals should have caused SJS to evaluate alternative explanations for the McGovern study's reporting of a purported "association" between the Bair Hugger system and increased surgical site infections. And those danger signals require this Court to carefully scrutinize the McGovern study and its underlying data, just as the courts did with the plaintiffs' general causation experts' key studies in the Viagra and Baycol MDLs.

First, the McGovern study was an observational study, meaning that it was not blinded and controlled like a clinical study. "[O]bservational studies are more susceptible to bias and other confounding factors, and so are less reliable than clinical studies, which

are often referred to as the 'gold standard.'" *Prempro*, 738 F. Supp. 2d at 891. Indeed, as Samet conceded, the McGovern study is the least reliable type of observational study: an interrupted time series, or "ITS." DX25, Samet Dep. at 93:13-14. In an ITS, data are collected before and after an intervention to detect whether the intervention has had an effect significantly greater than the secular trend. *See* DX44, Ramsay et al., "Interrupted Time Series Designs in Health Technology Assessment: Lessons from Two Systematic Reviews of Behavior Change Strategies," 19(4) *Int. J. Tech. Assess. Health Care* 613 (2003) (concluding that "ITS designs are often analyzed inappropriately, underpowered, and poorly reported").[10]

Second, the McGovern study reports only an "association." Association is not causation. *Reference Manual on Scientific Evidence* at 221 (3d ed. 2011); *see also In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig*, MDL No. 2:14-mn-02502-RMG, 2016 WL 8739552, at *10 (D.S.C. Dec. 29, 2016) (collecting cases).

[10] As co-author Dr. Reed testified, the observational component of the McGovern study was "opportunistic." DX32, Reed Dep. at 25:14-25. The authors decided to look at infection data only after they conducted their bubble experiment, which was itself undertaken only after their Augustine-funded study of the actual impact of the Bair Hugger on particles and bacteria failed to demonstrate any effect from the Bair Hugger. The initial bacteria and particle study, which was never published, demonstrated that the Bair Hugger had *no impact* on particles or bacteria; *i.e.*, the number of particles and bacteria reaching the surgical site in a laminar flow operating room was the same whether the Bair Hugger was on or off. DX27, McGovern et al., "Do Forced Air Warming Devices Increase Bacterial Contamination of Operative Field? – Simulated experiment analysis" (Unpublished). (This undisclosed earlier study is the one Defendants referenced on page 15 of their opening memorandum. Contrary to Plaintiffs' argument, Defendants did not mean to imply that the published "bubble" component of the McGovern study reached this conclusion. *Cf.* Opp. at 24.)

Third, the McGovern authors expressly disclosed several possible confounding variables that prevented them from reaching a conclusion that the Bair Hugger system causes surgical site infections, including unspecified "infection control measures," a major change in drug regimen during the study period, and differences in patient risk factors:

> ***This study does not establish a causal basis for this association***. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and ***may be confounded by other infection control measures instituted by the hospital***. For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection control changes were made after February 2010.
>
> In addition, ***we were unable to consider all factors that have been associated with SSI***, as the details of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection, were not sufficiently detailed in the medical record.

DX11, McGovern at 1543 (footnotes omitted and emphasis added). *See In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig*, 524 F. Supp. 2d 1166, 1173 (N.D. Cal. 2007) ("The downside to observational studies is that because the investigators do not control who participates in the study, it is more difficult to control for confounding factors such as smoking, obesity and the like.").

Fourth, the co-author who performed the statistical analysis for the McGovern study, Mark Albrecht, was an employee of a competitor, Scott Augustine. This would not have been known to the peer reviewers of the McGovern study,[11] but certainly was known

[11] Albrecht is identified in the published paper as a "graduate student in statistics" at the University of Minnesota. Indeed, he was a student at the University of Minnesota – part

to Plaintiffs' counsel and communicated to Plaintiffs' experts. DX25, Samet Dep. at 66:16-24 ("Q. Well, did you – did – Were you aware he did the statistical analysis in the McGovern paper? A. I'm aware of that, yes. Q. And are you aware that he worked for Scott Augustine's company, Augustine Medical? A. I'm aware that he did.").[12]

And fifth, the McGovern study does not even answer the question that Plaintiffs' experts were asked to answer. It compares the infection rates of surgeries using the Bair Hugger system with surgeries using Augustine's HotDog system. It does not compare the Bair Hugger system to the background infection risk. As Dr. Borak notes, "[e]ven if there were sufficient evidence to conclude a difference between two alternative warming methods, it would not necessarily indicate that the inferior method 'caused' the adverse outcomes (i.e., SSI). Instead, it might be a question of the relative efficacies of two beneficial methods." DX9, Borak Rpt. at 4 n.1. Courts have repeatedly held that a general causation expert must consider background risk – which in this case would be infection rate with no warming. *See In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d 1345,

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time, and financed by Augustine, while employed by Augustine. DX28, Albrecht Dep. at 18:12-25. The "conflict of interest" statement at the end of McGovern vaguely alludes to the existence of some undisclosed relationship: "The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article." DX11, McGovern at 1544.

[12] As detailed in Defendants' motion to exclude Plaintiffs' engineering experts, McGovern was part of a suite of studies concocted, conceived, orchestrated, and implemented by Scott Augustine as part of his plan to destroy the Bair Hugger system and increase the sales of his competitor product, the HotDog, by generating and publishing phony science and collaborating with Plaintiffs' lawyers to bring litigation based on that phony science. McGovern is the crown jewel to emerge from what Albrecht aptly described as the "publication factory." DX29, 7/9/2010 Email from Albrecht to Reed at 1.

1355 (S.D. Fla. 2011) (citing Michael D. Green et al., *Reference Manual on Scientific Evidence* 336 (2d ed. 2000); *McClain v. Metabolife Intern., Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005)), *aff'd*, *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296 (11th Cir. 2014).

Even a few of these danger signals were sufficient justifications for Plaintiffs' experts to scrutinize the underlying data. Dr. Borak, a professor of epidemiology at Yale, explains that "[t]o be meaningful, an inference of causality necessarily assumes that the evidence and data supporting that inference are valid. Likewise, if the underlying facts are not valid, then it follows that inferences which rely on those facts would also not be valid." DX9, Borak Rpt. at 5. An expert making an inference of causality must therefore assess the "internal validity" of a study before making causal inferences. Assessing internal validity requires consideration of confounders and bias. DX9, Borak Rpt. at 6; *see also* Michael D. Green et al., "Reference Guide on Epidemiology," *Reference Manual on Scientific Evidence* 549, 598 (3d ed. 2011) ("In assessing causation, researchers first look for alternative explanations for the association, such as bias or confounding factors . . . ."); *id.* at 612-13 (noting that the propriety of using epidemiology to infer causation depends upon evaluating whether confounding factors are the source of the association). And, of course, internal validity also depends on the data being correctly presented. DX9, Borak Rpt. at 20. If Plaintiffs' experts had followed the scientific method and properly assessed McGovern's internal validity, they would have discovered exactly what Defendants' experts discovered: serious tabulation errors, data manipulation, and confounding variables

that vitiate statistical significance and any basis for drawing a valid conclusion about association (let alone causation).

If this Court is inclined to overlook SJS's methodological failure, it must itself do what SJS failed to do and carefully analyze the McGovern study and its underlying data. For this, it should look to the unrebutted analyses of Prof. Holford and Dr. Borak, which demonstrate that McGovern's flaws are deep, consequential, incapable of remediation, and so fundamental as to vitiate reliability.

B. The Data Underlying the McGovern Study Were Manipulated to Increase the Odds Ratio and Achieve Statistical Significance.

1. Prof. Holford's biostatistical analysis demonstrates that the McGovern data were misreported and that there was no statistically significant difference in infection rates.

Prof. Holford, Defendants' biostatistics expert, reanalyzed the data underlying the McGovern study.[13] As Holford explains, the underlying data do not match the published study. The data show one fewer infection in the Bair Hugger period and one additional infection in the HotDog period than reported. When the data are reanalyzed to account for this error, there is ***no statistically significant difference in infection rates*** between the Bair Hugger system and the HotDog. DX10, Holford Rpt. at 2, 8 ("Correcting this tabulation

[13] In an attempt to excuse their experts' failure to analyze the data, Plaintiffs deny that the data Holford analyzed are, in fact, the actual data underlying the McGovern study. Plaintiffs' attack is contradicted by the discovery record and their own recent representations to the Court. As explained at length in Defendants' opposition to Plaintiffs' motions to exclude the opinions of Holford and Borak, all the evidence in the case strongly supports the conclusion that the data Holford analyzed (which were produced by Augustine in response to Defendants' subpoena) are the real underlying McGovern data.

changes the test for significance from statistically significant to not statistically significant . . . . The confidence interval is wide and actually includes the null value of 1.").

Comparing the data set with additional data produced by Dr. McGovern, Prof. Holford was able to determine the origin of the tabulation error. All the procedures identified as taking place during the Bair Hugger period are identified as "FAW" in the data produced by McGovern, but only three of the four procedures occurring during the HotDog period are coded as "CWB." *Id.* at 3. One procedure (September 15, 2010) is coded as "FAW," meaning that it was counted as a Bair Hugger infection. *Id.* And that is the problem: September 15, 2010 was long after Northumbria (the English trust that operated the hospital studied by McGovern) fully transitioned from Bair Hugger to HotDog and was the exact midpoint of what the McGovern study reported as the HotDog period.[14]

Holford further demonstrates that this recoding of a HotDog infection as a Bair Hugger infection likely occurred in the United States, after the UK-based lead researcher, Dr. Reed, sent the data to Augustine's employee, Mark Albrecht. All the initial entries' dates on the data produced by McGovern are presented in the standard British format of date, month, year. *Id.* These are identical to the same entries on the data produced by Augustine for the corresponding procedure. On the final pages of the McGovern-produced data, however, where the "FAW" or "CWB" coding is entered, the procedure dates are repeated but entered in the standard American format of month, date, year. *Id.* Albrecht

[14] Dr. McGovern could not explain why a procedure occurring in the middle of the HotDog period would have been coded as "FAW" (*i.e.*, as a Bair Hugger infection). DX31, McGovern Dep. at 481:6-484:6.

apparently coded the warming devices on an Excel spreadsheet that had culled out only those procedures that resulted in infections. Whether by error or by intention, the September 15, 2010 procedure was miscoded, apparently by Albrecht, as "FAW" (Bair Hugger) when it should have been "CWB" (HotDog). As Holford concludes, this miscoding made the difference between lack of statistical significance and statistical significance. DX10, Holford Rpt. at 2.

Plaintiffs would like the Court to ignore Prof. Holford's analysis, but Holford is not alone in finding tabulation errors in the McGovern data. The McGovern study's authors knew of tabulation errors and that the reported odds ratio of 3.8 was substantially higher than the actual data supported. Dr. Reed testified that there was an additional infection in both the Bair Hugger and HotDog groups that had, despite his communications with Albrecht, not been corrected prior to publication.[15] DX8, Reed Dep. At 42:23-44:9. Reed's testimony was, of course, available to Plaintiffs' experts – and is, in fact, listed among Samet's materials considered. DX2, Samet Rpt. Ex. C.

[15] The actual data suggest that Reed's recollection of the nature of the tabulation error is not quite accurate: there was actually one fewer Bair Hugger infection, rather than one additional infection in both the Bair Hugger and HotDog groups. But for the sake of completeness, Holford accounted for the possibility that Reed's recollection was correct. Holford performed an additional statistical analysis assuming the accuracy of Reed's recollection. Based on Reed's testimony, he calculated an odds ratio of 2.86 with a wide confidence interval *just barely* above statistical significance. DX10, Holford Rpt. 3 n.1. Holford's belt-and-suspenders analysis of Reed's almost-certainly-mistaken recollection is not, by any stretch of the imagination, an admission by Holford of a "significant relationship between use of Bair Hugger" and surgical infections, as Plaintiffs contend. Opp. at 36.

Plaintiffs' experts also ignored the written communications between Reed and Albrecht, which show that they knew that data in the published article differed from an updated dataset that Reed sent to Albrecht. DX33, 5/27/2012 Emails between Albrecht and Reed. In these private communications that were never disclosed to the peer reviewers, Albrecht recalculated the odds ratio with the updated data and found that it was 2.98 (a number that Holford shows is still incorrect), not 3.8 as reported in the published study. *Id.* The bottom line is that the odds ratio reported in the published study and relied upon by Plaintiffs' experts is, by its authors' own admissions, ***wrong***. Tabulation errors occurred, the tabulation errors resulted in an inflated odds ratio, and neither McGovern's authors nor Plaintiffs' experts offer any correction or explanation for this major discrepancy.

It is this type of serious data error, uncovered during discovery, that caused the court in the Viagra MDL to revisit its initial *Daubert* decision (the decision Plaintiffs repeatedly cite without noting its subsequent history). *See Viagra II*, 658 F. Supp. 2d at 950. Of course, peer reviewers who had no knowledge of the tabulation errors or access to the underlying raw data could not have detected the errors identified by Holford. As the *Viagra* court noted, "[p]eer review and publication mean little if a study is not based on accurate underlying data." *Id.* at 945; *see also Daubert*, 509 U.S. at 594 (publication in a peer-reviewed journal is "not dispositive").

Plaintiffs make one final, remarkable argument on the data mistabulation. They argue that Holford's reanalysis of the McGovern data *proves* not only general causation but also specific causation, because it still results in an odds ratio above 2.0 (albeit without

statistical significance). Opp. at 36 & n.11. They cite no case that has ever concluded that a study that suffers from data manipulation is reliable. But in any case, Plaintiffs' argument ignores the remainder of Prof. Holford and Dr. Borak's analysis, which further vitiates the McGovern study's reported "association" between the Bair Hugger system and surgical site infections.

2. Holford's biostatistical analysis and the McGovern study drafts demonstrate that the McGovern authors manipulated the start date to achieve statistical significance.

The tabulation error identified by Prof. Holford is just the beginning of the McGovern study's problems. Prof. Holford's analysis also strongly suggests that the start date of the period analyzed by the McGovern study was altered to July 1, 2008 as a measure to strengthen the reported "association" and achieve statistical significance. Prof. Holford conducted a statistical analysis of the data using start dates of each successive month, beginning in October 2007. As demonstrated in Holford's Figure 3, significance is not achieved for any month prior to July 1, 2008. DX10, Holford Rpt. at 5, 13. And if the start date had been two months *later*, statistical significance would not have been achieved either. *Id.*

The early drafts of the McGovern study – which were available to, but not considered by Plaintiffs' experts – indicate that the start date used in the published study was purposely selected to achieve statistical significance. The first draft states, "Joint sepsis data was collected for all orthopedic operations performed in the hospital during the 2-year period prior to the study, with dates comprising ***9/1/2008 to 9/1/2010***." DX37, McGovern Drafts at 2206 (emphasis added). In the tenth draft, however, the authors

expanded the Bair Hugger period by moving the start date from September 2008 back to July 2008, the date used in the published paper that achieved (just barely) statistical significance. *Id.* at 2400-2422. As Holford demonstrates, it took moving the start date to achieve even minimal statistical significance. DX10, Holford Rpt. at 13. The change would, of course, also advance the "agenda" of Albrecht's employer, Augustine.[16]

As the Seventh Circuit has noted, "careful pretrial discovery" can demonstrate that apparent statistical significance is a "misleading artifact of the study's design." *Kadas v. MCI Systemhouse Corp.*, 255 F.3d 359, 362 (7th Cir. 2001). That is exactly what discovery of the drafts and the underlying data revealed here.

C. Plaintiffs' Experts Failed to Analyze the Impact of the Change in Antibiotics and Antithrombosis Drugs.

As discussed above, an expert who relies on an observational study to form a causation opinion – particularly an interrupted time series study like the McGovern study – ***must*** evaluate potential confounders and bias before concluding that the study is internally valid and reliable. *Reference Manual on Scientific Evidence* at 598 ("In assessing causation, researchers first look for alternative explanations for the association, such as bias or confounding factors . . . ."). The Court likewise must consider confounders and bias in determining whether the study is scientifically valid. *See* Fed. R. Evid. 702 Adv.

[16] Augustine, Albrecht, and their co-authors worked to "hide [the] agenda" of their publications and to appear "impartial." *See* DX38, 2/16-22/2011 Emails from McGovern to Albrecht at 5 ("You did a good job of hiding the 'agenda' and making this look much more impartial"); DX39, BHS Presentation Outline at 1 ("This makes it look impartial and hides our agenda, so to speak . . ."); DX40, 1/23/2010 Email from Albrecht to Leaper at 1 ("we need to be critically careful that this document appears to be impartial"); *see also* DX28, Albrecht Dep. 310:19-324:13.

Comm. Notes (2000) (in determining the reliability of an expert's opinion, courts consider "[w]hether the expert has adequately accounted for obvious alternative explanations"); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253 (6th Cir. 2001) ("Before any inferences are drawn about causation, the possibility of other reasons for the association must be examined, including chance, biases such as selection or informational bias, and confounding causes."); *Baycol*, 532 F. Supp. 2d at 1043 ("It is generally accepted that bias in the conduct of a study can materially affect the result and that detection and accounting for bias are standard tools of epidemiology."); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, MDL No. 2342, 2015 WL 314149, at *3 (E.D. Pa. Jan. 23, 2015) (noting that the court had excluded the testimony of plaintiffs' general causation expert in part because she failed to "adequately address certain confounding factors").

Here, the McGovern study's co-authors disclosed two potential confounders: changes to the antibiotic and antithrombotic drugs used with the study population. DX11, McGovern at 1543. SJS ignore or dismiss the possibility that these changes explain the association found in the McGovern study. Jarvis's and Stonnington's reports have nothing to say about the impact of the confounders disclosed in the McGovern study. Samet asserts that the 3.8 odds ratio reported by the study – an odds ratio already shown to be incorrect by Holford's analysis – is simply too big to be the result of confounders. DX2, Samet Rpt. at 12; PX13, Samet Dep. at 65:7-17. Samet does not identify, and Plaintiffs also do not identify, any time that he or Jarvis or Stonnington has previously given the opinion that a 3.8 odds ratio is too large to be the result of confounders. DX25, Samet Dep. at 80:11-81:1 (Samet concurs that, in the context of his tobacco work, his causation opinions were based

on consistency results in *multiple* observational studies with an odds ratio of at least 9, with some studies finding odds ratios higher than 20 or 30). Nor do Samet or Plaintiffs identify any scientific literature that would support Samet's position. His whole argument is pure *ipse dixit*.

The underlying data (which Samet never reviewed) show that Samet is wrong. When the two disclosed confounders are accounted for, the "association" between the Bair Hugger system and increased infection risk vanishes. Mark Albrecht, the Augustine employee who performed the data analysis for the McGovern study, conceded this point: there is no difference in infection rates when one controls for the disclosed confounders. DX12, Albrecht Dep. at 200:9-205:18. Albrecht's testimony was available to Plaintiffs' experts, yet even that did not cause them to analyze the potential impact of the confounders.[17] Prof. Holford's reanalysis of the data also confirms that there is no difference in infection rates when controlling for these confounders.

Plaintiffs object that Albrecht and Holford's reanalysis does not show that the impact of the individual confounders is statistically significant. They are wrong on this

[17] Plaintiffs assert that "Professor Holford collapsed on cross-examination, conceding that the scientific literature does not suggest a relationship between anti-thrombotic drugs and DJI." Opp. at 29 (citing PX1, Holford Dep. at 293:7-295:13). The Court will search Holford's testimony in vain for any "collapse" or "admission." Professor Holford certainly agreed that he had not reviewed the literature on that subject. He is a biostatistician. It is his role to conduct the data analysis. It is the role of his colleague, Dr. Borak, a medical doctor and professor of epidemiology, to review the antithrombosis literature, which he did at paragraphs 42 through 45 of his report. *See Reference Manual on Scientific Evidence* 215 (3d ed. 2011) (noting that statisticians typically are disclosed alongside a subject-matter expert, who considers the statistical analysis in light of the literature). Borak concludes that the literature "demonstrate[s] the importance of confounding by antithrombotic regimen and prophylactic regimen." DX9, Borak Rpt. at 16.

point as well. Rivaroxaban is independently statistically significant, as Prof. Holford demonstrates in his unrebutted report. DX10, Holford Rpt. at 5-6. Moreover, both Borak and Holford explain why a confounder need not be demonstrated to have a "statistically significant" impact on an outcome for it to nonetheless be considered a confounder. PX1, Holford Dep. at 280:9-282:4 ("[Y]ou could have associations that are not -- that don't achieve statistical significance but they do in fact behave as confounders in that they change the association when you adjust for them. And it can go either way, it can go -- make a very weak association stronger or it can make a strong association go away."); DX34, Borak Dep. at 148:13-22 ("[W]hether something is or is not a confounder is not dependent on whether it is, on a univariate level, statistically significantly associated with the outcome or whether it significantly influences the relationship that it confounds.") This is a basic premise accepted in biostatistics and epidemiology and, in fact, conceded by Samet. DX25, Samet Dep. at 50:2-9 ("Q. And in order for you to have determined that something is a confounder -- correct me if I'm wrong. But it's your -- your expert opinion that a particular risk factor has to independently achieve statistical significance. Otherwise, it -- it is disregarded, it doesn't have an impact, it has no results. A. ***It does not necessarily have to achieve statistical significance to be a confounder***." (Emphasis added)). Plaintiffs' contrary position finds no support in the scientific literature or in their own experts' opinions.

1. Change in Antithrombosis Drugs.

In their Opposition, Plaintiffs argue that the changes in antithrombosis drugs and antibiotics could not be confounders, citing either scientific literature or the testimony of a

McGovern study co-author. Opp. at 27-28, 37-39. But Plaintiffs' arguments are contradicted by the scientific literature, including the literature upon which they rely.

At the beginning of the Bair Hugger period of the McGovern study, all patients were given tinzaparin as thromboprophylaxis (to prevent blood clots). DX11, McGovern at 1540. Several months after changing the antibiotics, but prior to switching to HotDog, the hospital switched the antithrombosis regimen to rivaroxaban. However, after seven months, the complication rate from rivaroxaban was so high that the hospital switched back to using tinzaparin. DX32, Reed Dep. at 92:8-95:10. The full seven months of rivaroxaban use occurred during the Bair Hugger period; indeed, it coincided with the end of the Bair Hugger period. Therefore, all HotDog patients had the benefit of tinzaparin. Prof. Holford demonstrates that a major spike in infections occurred during the seven months rivaroxaban was used. DX10, Holford Rpt. at 5. As Defendants' expert Dr. Richard Wenzel also explains in his report, the use of rivaroxaban during the Bair Hugger period alone introduces bias into the study, which is a fatal flaw. DX45, Wenzel Rpt. at 63.

In defense of their experts' failure to account for this bias, Plaintiffs cite to the testimony of Dr. Reed, the McGovern study co-author, claiming that he testified, based upon another study, that "we can [now] exclude Xarelto [the trade name of rivaroxaban] as a confounding factor for infection rates." Opp. at 28 (citing PX15, Reed Dep. at 215:14-18). Unlike Plaintiffs' experts, Holford carefully analyzed Reed's other study (referred to here as "Jensen"). PX26, Jensen et al., "Return to Theatre Following Total Hip and Knee Replacement, Before and After the Introduction of Rivaroxaban," 93-B(1) *J. Bone & Joint Surgery* 91, 93 (2011). He noted that the Jensen study had a shorter window for infection

surveillance than McGovern (30 versus 60 days) and included not only elective joint surgery, but also trauma surgery. DX10, Holford Rpt. at 5. McGovern excluded trauma patients because of the much higher rate of infection. *Id.*; *see* DX32, Reed Dep. at 60:6-63:15. Knowing the dates of rivaroxaban use as reported in both Jensen and McGovern, Holford demonstrates that four of the infections reported in the Bair Hugger cohort during the period when rivaroxaban was used occurred between 30 and 60 days following surgery. Thus, those four infections were not included in the 14 infections reported in Jensen's rivaroxaban group. Holford applies McGovern's surveillance period (60 days) and its trauma-exclusion criterion to Jensen's dataset, which results in a ***highly significant impact*** of rivaroxaban on deep joint infections. DX10, Holford Rpt. at 5. This is what Plaintiffs' experts would have found if they had bothered to analyze the data.

2. Change in Antibiotics.

The other confounder disclosed by McGovern, and addressed by Defendants' experts Holford, Borak, and Wenzel, is antibiotic prophylaxis. McGovern notes that patients at the beginning of the Bair Hugger period were given only one prophylactic antibiotic: gentamicin. DX11, McGovern at 1540. Several months into the Bair Hugger period, a second antibiotic, teicoplanin, was added to the regimen. This regimen remained constant for the remainder of the Bair Hugger period and through the HotDog period. *Id.*

Attempting what their experts failed to do, Plaintiffs cite another paper co-authored by Reed ("Hickson"), which they claim finds that "there is no clear benefit to using one particular agent/regimen." Opp. at 28 (citing PX21, Hickson et al., "Prophylactic Antibiotics in Elective Hip and Knee Arthroplasty," 4(11) *Bone & Joint Res.* 181, 186

(2013)). Plaintiffs say this means that the combination of teicoplanin and gentamicin (the drug regimen to which Northumbria switched during the Bair Hugger period) is no more effective than gentamicin alone, the antibiotic protocol in place during the first seven months of the Bair Hugger period. But Plaintiffs' assertion is contradicted by language on the same page of Hickson. Hickson notes that while there is a "large body of evidence" supporting prophylactic antibiotics, "[t]here is no evidence for the use of systemic gentamicin as prophylaxis in primary elective THA and TKA surgery." PX21, Hickson at 186.

Given that Dr. Reed co-authored the Hickson study, this unambiguous conclusion was almost certainly informed by Reed's own experiences at Northumbria during the period of the McGovern study. Reed's experiences are also detailed in another published paper that Dr. Borak addressed but that Plaintiffs and their experts have ignored: DX35, Sprowson et al., "Changing Antibiotic Prophylaxis for Primary Joint Arthroplasty Affects Postoperative Complication Rates and Bacterial Spectrum," 11 *Surgeon* 20 (2013); DX9, Borak Rpt. at 13 & n.25 (discussing Sprowson).

Sprowson examined complications, including wound infection, in joint arthroplasty at Northumbria from January 2002 to February 2009, a period that involved a switch from cefuroxime to gentamicin. DX35, Sprowson at 20. Cefuroxime had been used at Northumbria with great success; however, reducing clostridium difficile-associated diarrhea (CDAD) became a national priority. *Id.* at 20-21. As part of Northumbria's CDAD improvement plan, antibiotic prophylaxis for primary arthroplasty was changed from cefuroxime to gentamicin in October 2007. *Id.* at 21. As the McGovern study

indicates, Northumbria changed from gentamicin-only to gentamicin-plus-teicoplanin in March 2009.

Sprowson sheds light not only on the importance of the right combination of antibiotics in preventing deep joint infections, but also on the lack of any involvement of the Bair Hugger in causing them. In the nearly six years of cefuroxime use examined by Sprowson's authors, involving 6,094 patients undergoing primary knee and hip arthroplasty, the return to theatre (RTT) for proven infections was only 0.66 percent. *Id.* In the 17 months of gentamicin-only use reviewed in the Sprowson paper, involving 2,101 patients receiving a single dose of gentamicin, the RTT rate for proven infection jumped to 1.52 percent. *Id.* This difference was statistically significant ($P < 0.01$). *Id.* Reed and his co-authors concluded:

> [G]entamicin 4.5 [milligrams per kilogram] alone should not be used as prophylaxis for primary joint arthroplasty as it does not reduce CDAD significantly but increases the risk of other postoperative complications. We have changed our prophylaxis to low dose gentamicin (3 mg/kg) combined with teicoplanin 400 mg given once.

Id. at 20.

Sprowson is important for at least two reasons. First, it examined infection rates at the Trust that includes the same hospital that McGovern studied. Second, a portion of the patients Sprowson examined included the same patients who comprised the first seven months of the Bair Hugger period in the McGovern study. All of the more than 8,000 surgeries in Sprowson, however, occurred when the Trust was using Bair Hugger exclusively. When using cefuroxime, the infection rate was only 0.66 percent. After

switching to gentamicin, the infection rate nearly tripled, to 1.52 percent. This statistically significant increase prompted a change in the antibiotic regimen seven months into the Bair Hugger period.

Sprowson further refutes Plaintiffs' unfounded contention that the antibiotic regimen is not a confounder. Using gentamicin alone nearly ***tripled*** the infection rate over another antibiotic, prompting Northumbria to change its antibiotic regimen. Further, when the more effective antibiotic cefuroxime was used in conjunction with the Bair Hugger, the joint infection rate was a mere 0.66 percent, markedly lower than the rate "achieved" by switching from Bair Hugger to HotDog.[18]

D. Plaintiffs' Experts Failed to Consider the Massive Infection Control Initiative That Benefited Mostly HotDog Patients.

McGovern co-author Reed testified that massive efforts were being undertaken by the Northumbria Healthcare NHS Trust at the time of the McGovern study to decrease its infection rates. DX8, Reed Dep. at 78:3-79:2, 108:25-109:11, 112:18-113:22, 114:7-25, 115:11-119:6. Plaintiffs' experts had Dr. Reed's testimony available to them, but they failed to consider the impact of these initiatives.

By contrast, as part of evaluating the internal validity of the McGovern study, Dr. Borak discusses several of the infection control initiatives and the potential impact that they have on McGovern's findings. DX9, Borak Rpt. at 10-12. Borak explains that these

[18] Tinzaparin had been the thromboprophylaxis at Northumbria from October 2006 until a brief and disastrous switch to rivaroxaban, prompting a return to tinzaparin. DX36, Khan et al., "Reduced short-term complications and mortality following Enhanced Recovery primary hip and knee arthroplasty: results from 6,000 consecutive procedures," 85(1) *Acta Orthopaedica* 26, 27 (2014).

confounders plague the McGovern study, dramatically undermining the validity of its conclusions, and Dr. Samet's reliance upon it. *Id.* at 19. Plaintiffs' rejoinder boils down to this: unless an infection control practice has been conclusively demonstrated to have a statistically significant impact on *overall* infection rates by itself, it cannot be a real confounder. Opp. at 37-38. As discussed above, that rejoinder has no basis in science. Holford and Borak explain – and Samet agrees – that a variable can be a confounder without reaching statistical significance.

Dr. Borak's report explains that research related to the McGovern study further demonstrates the significance of the infection control measures implemented at Northumbria. One of the studies cited by Borak is R. Refaie, "Prevention of Periprosthetic Joint Infection," 3(3) *J. Trauma & Orthopedics* 50 (Sept. 2015) ("Refaie") (DX46). DX9, Borak Rpt. at 13 & n.32. Also co-authored by Dr. Reed, the Refaie study discusses prewarming, a practice instituted at Northumbria at the same time the HotDog was introduced – so no Bair Hugger patients would have had the benefits of prewarming, while all HotDog patients would have:

> Prewarming of patients before theatre is a proven strategy for preventing hypothermia intraoperatively and in recovery. A large RCT from the UK published in the Lancet showed that prewarming reduced the risk of infection by around 65% in clean surgery. Despite this, prewarming is still not widely adopted in UK centers.

DX46, Refaie at 51.

Refaie also describes Northumbria's experience in implementing screening for Methicillin Susceptible *Staph. aureus* (MSSA) – a practice instituted during the Bair Hugger period:

> After MSSA screening and decolonization was introduced in one NHS joint replacement unit, MSSA infections reduced from 0.84% to 0.26% – the caveat being there were other infection prevention methods implemented during this time period.

Id. This statement's footnote demonstrates that Northumbria was the NHS joint replacement unit to which Refaie was referring. Refaie thereby confirms that the MSSA infection rate dropped by more than two-thirds when MSSA screening and decolonization was implemented at Northumbria. Because MSSA screening was not implemented until January 2010, most Bair Hugger patients in the McGovern study would not have had the benefit of MSSA screening. Most Bair Hugger patients had their surgery conducted at a time when the MSSA infection rates were themselves nearly one percent. By contrast, every one of the HotDog patients would have benefited from MSSA screening and decolonization which, according to Refaie, caused MSSA infection rates to plummet. Significantly, *none* of the infections in the HotDog period were *staph. aureus*, while nearly one-third of the Bair Hugger infections pre-MSSA screening were *staph. aureus*.[19]

Plaintiffs' medical experts failed to consider any of this research before dismissing the possibility that Northumbria's infection control measures could have confounded the results of the McGovern study.

[19] Samet also conceded that gentamicin alone would not be particularly effective against staph. aureus, but teicoplanin would. DX3, Samet Dep. at 98:12-99:1. And indeed, it was.

E. With or Without the McGovern Study, Plaintiffs Cannot Establish General Causation.

There is no dispute that SJS depend on the McGovern study to quantify the purported increased risk of surgical infections when the Bair Hugger system is used. It is enough, Plaintiffs argue, for their experts to simply conclude that the Bair Hugger system "increases risk" without quantifying that risk. Case law is to the contrary. Courts have repeatedly concluded that the increased risk ***must*** be quantified, and that an expert's reliance on a study that lacks statistical significance suggests that the expert's methods are unreliable.

The *Daubert* litigation is a prime example. In the post-remand proceedings in *Daubert*, the Ninth Circuit re-considered the scientific evidence relied upon by the plaintiffs' experts and found it to be inadequate to support their causation opinions. *Daubert II*, 43 F.3d at 1321-22. It determined that the district court had correctly found that "the strongest inference to be drawn for plaintiffs based on the epidemiological evidence is that Bendectin could possibly have caused plaintiffs' injuries." *Id.* at 1322. It also determined that the animal studies and chemical structure analyses relied upon by the plaintiffs' experts "testify to a possibility rather than a probability." *Id.* It then explained the fatal flaw: "Plaintiffs do not quantify this possibility, or otherwise indicate how their conclusions about causation should be weighted, even though the substantive legal standard has always required proof of causation by a preponderance of the evidence." *Id.* Similarly, in *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 (11th Cir. 1999), the Eleventh Circuit affirmed the district court's exclusion of a medical causation expert who

relied on a study with an odds ratio of 1.24, "a finding so significantly close to 1.0 that the court thought the study was not worth serious consideration for proving causation." *See id.* at 1315 n.16 ("[W]e do not think the district court abused its discretion in finding a 1.24 risk minimal in terms of causation. Moreover, showing association is far removed from proving causation.").

Thus, without a reliable odds ratio upon which to base their opinions, there is no way for the factfinder to weigh SJS's general causation conclusions. Where, for example, state law requires scientific proof that the Bair Hugger is a "substantial contributing cause" to surgical site infections, the factfinder cannot determine whether the "increased risk" is substantial or not substantial without an odds ratio. *See Samaan v. St. Joseph Hosp.*, 670 F.3d 21, 34-35 (1st Cir. 2012) (concluding that causation expert's odds ratio of 1.5 "does not support a finding of causation under Maine law," which employs a substantial factor causation standard, and therefore was inadmissible under *Daubert* and Fed. R. Evid. 702). This is not merely a problem limited to individual bellwether cases, because Plaintiffs have repeatedly made clear from the beginning of this litigation that they intend to rely on McGovern's reported odds ratio to establish causation in ***all*** cases in the MDL and Ramsey County. *See, e.g.*, Opp. at 30-32. *See Lipitor*, 2016 WL 8739552, at * (an odds or hazard ratio "is the very definition of an association, and says nothing about causation").

On the issue of statistical significance: "[c]ourts have emphasized that epidemiologic proof must be statistically significant." *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 461 (W.D. Pa. 2003) (collecting cases). Even those courts that have not applied a bright-line rule still exclude experts who rely heavily on non-statistically

significant epidemiology. *Prempro* is an example. There, the court excluded the plaintiff's general causation epidemiology expert, in part, because he relied on findings in studies that lacked statistical significance. Judge Ann Montgomery and Eastern District of Arkansas Judge William R. Wilson, Jr. noted in their joint opinion that "as many federal courts observe, if an expert places undue emphasis on statistically insignificant evidence, it may indicate that the expert's methods are unreliable." *Prempro*, 738 F. Supp. 2d at 892 (citing *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 380 & n.23 (5th Cir. 2010); *Pritchard v. Dow Agro Scis.*, 705 F. Supp. 2d 471, 489-90 (W.D. Pa. 2010)).

Holford's unrebutted reanalysis of the underlying data demonstrates that there is, in fact, no statistically significant difference in infection rates between the Bair Hugger and HotDog periods. DX10, Holford Rpt. at 2. There can be no dispute that SJS depend on the McGovern study for their inference of causation, despite its now-established failure to demonstrate a statistically significant association between Bair Hugger use and surgical site infections. This further underscores the unreliability of SJS's opinions. *See, e.g.*, *McMunn v. Babcock & Wilcox Power Generation Group, Inc.*, 2013 WL 3487560, at *15 (W.D. Pa. July 12, 2013) ("If no association between the exposure and the disease is supported by the scientific literature, there is no basis to find a causal relationship exists and the analysis should end there."); *Dunn v. Sandoz Pharm. Corp.*, No. 10-143275, F. Supp. 2d 672, 679 (M.D.N.C. 2003) (excluding general causation opinion of expert who purported to could not cite any epidemiological studies showing association between substance and disease at issue).

III. SJS DID NOT APPLY THE SAME LEVEL OF RIGOR AS THEY DO TO THEIR NON-LITIGATION WORK.

A. Plaintiffs' Opinions Do Not Grow Out of Their Own Independent Research.

SJS's testimony should also be excluded because they are not testifying about "matters growing naturally and directly out of research they have conducted independent of the litigation." Fed. R. Evid. 702 Adv. Comm. Notes (2000) (quoting *Daubert II*, 43 F.3d at 1317). Neither Samet, nor Jarvis, nor Stonnington has ever conducted a study to determine whether the Bair Hugger causes surgical site infections.

Samet and Jarvis undisputedly "developed their opinions expressly for purposes of testifying," *Daubert II*, 43 F.3d at 1317, having never previously considered whether the Bair Hugger system causes surgical site infections. Neither previously concerned himself with the safety or efficacy of patient warming devices. Moreover, Dr. Samet, the only one of Plaintiffs' experts who quantifies the purported increased risk of infection, offers no example of any time in his professional career that he has ever given the opinion that *anything* causes injuries based on a single observational study with an odds ratio of 3.8. (And, as explained above, the McGovern study's odds ratio of 3.8 was erroneous and based upon a serious tabulation error – a fact Samet would have discovered if he had bothered to look at the data.[20])

[20] DX25, Samet Dep. at 41:5-8 ("Q. And you have looked at all of the underlying raw data that had -- hadn't been made available to anyone for that McGovern paper; right? A. I did not look at the actual raw data.").

Stonnington purportedly formed his causation opinion before he was formally retained as a testifying expert by Plaintiffs (though still *after* he had discussed the case with Plaintiffs' counsel in 2015), but he conducted no independent *research* to support that opinion before this litigation. His only basis for his pre-retention opinion was his personal observations (that is, his speculation), unsupported by any study or data that has been disclosed in this litigation.[21] DX7, Stonnington Dep. at 39:12-40:14, 96:14-16, 269:13-270:6.

SJS's "methodology" here contrasts sharply with their non-litigation work. *See Kumho Tire*, 526 U.S. at 152 (stating that an expert must "employ[ ] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). Jarvis is illustrative. Jarvis offers the opinion that most pathogens that cause surgical site infections are "exogenous" (from sources outside the patient). As explained in Defendants' opening memorandum, Jarvis wrote in the 1999 CDC Guideline for Prevention of Surgical Site Infection that the majority of pathogens were endogenous (from the patient him- or herself). DX19, CDC Guideline at 103 ("For most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera."). When asked at his deposition how he explains this radical change of viewpoint,

[21] Plaintiffs mischaracterize Stonnington's personal recollections and observations as "case reports" and "challenge/dechallenge" data. Opp. at 58, 61. Stonnington did not produce any case reports or challenge/dechallenge data. Indeed, they are really "unreported case reports" at best. In any event, as *Glastetter* held, case reports, plus rechallenge and dechallenge events, plus inconclusive medical research still do not add up to "persuasive scientific evidence" sufficient to support a general causation expert opinion. *Glastetter*, 252 F.3d at 989-91.

he offered only his years of experience at the CDC. DX5, Jarvis Dep. at 163:17-23. But by the time he wrote the 1999 CDC Guideline, he had already been at the CDC nearly 20 years. *Id.* at 163:24-164:5. He could not cite any developments in his final three years at the CDC or any subsequent scientific literature that explains his change of viewpoint. *Id.* at 164:7-25. Plaintiffs declare that the 1999 Guideline was "based on limited information" (Opp. at 56), but also fail to identify any subsequent research that could justify his shift.

Plaintiffs also fail to explain the stark difference between how Jarvis approached this litigation and a 1990 study of deep joint infection rates at a Tennessee hospital. In the 1990 investigation, he used the CDC's "gold standard" methodology to rule out the various possible explanations for the outbreak, including patient fitness for surgery and other risk factors. Yet Jarvis failed to consider these same factors in evaluating and ultimately relying on the McGovern study. DX5, Jarvis Dep. at 216:8-16, 228:14-229:1; *see also* DX11, McGovern at 1543 (stating that "we were unable to consider . . . fitness for surgery").

B. SJS's Extrapolation from Existing Scientific Literature Was Unjustified.

Another one of the factors for the Court to consider is "whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion." Fed. R. Evid. 702 Adv. Comm. Notes (2000).

As explained above, Plaintiffs do not extrapolate from an accepted premise. Not one of the studies relied upon by SJS in their reports finds that the Bair Hugger system causes surgical site infections. The one weak observational study that finds an association, the McGovern study, expressly ***disclaims*** any finding of causation, identifies probable

confounding variables, and calls for further research. DX11, McGovern at 1543 ("This study does not establish a causal basis for this association."). As Dr. Borak explains, the McGovern study is "inconsistent with the reported results of other studies that found no association between BH [Bair Hugger] and SSI [surgical site infections]." DX9, Borak Rpt. at 21. And the independent authorities who have reviewed the body of literature, including ECRI, AORN, and the FDA, have consistently rejected the conclusion that the Bair Hugger system causes surgical site infections. *See Kumho Tire*, 526 U.S. at 152; *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 884 (10th Cir. 2005) (experts' methods were "not medically or scientifically valid" when experts "completely ignored or discounted without explanation" studies contradicting their conclusions).

Plaintiffs' experts nonetheless assert there is "consistency" across the literature, which supports their inference of causation. But as Samet himself states in his report, consistency "is generally applied as a consideration related to interpretation of findings of ***multiple observational studies***." DX2, Samet Rpt. at 16 (emphasis added). For example, the report of the Advisory Committee to the Surgeon General on smoking concluded that smoking causes lung cancer based upon consistent results in 29 retrospective observational studies and 7 prospective observational studies. DX9, Borak Rpt. at 20-21; DX25, Samet Dep. at 80:3-14. Here, by contrast, McGovern is the ***only*** observational study that SJS rely upon for the opinions set forth in their reports. *Reference Manual on Scientific Evidence* at 221 (3d ed.) (observational studies may provide evidence of causation when "[t]he association is seen in studies with different designs, on different kinds of subjects, and done by different research groups. That reduces the chance that the association is due to a defect

in one type of study, a peculiarity in one group of subjects, or the idiosyncrasies of one research group."). There can be no "consistency" across a set of one. Moreover, any assertion of "consistency" collapses when considering the full body of the scientific literature.

Neither SJS nor Plaintiffs can explain what reliable methodology would justify their flying leap from McGovern's limited finding of association (and disclaimer of causation and disclosure of confounders) to their opinions that the Bair Hugger causes surgical site infections. The only connection between the two is their own say-so. "A court may conclude that there is simply too great an analytical gap between the data and the opinion offered." *Joiner*, 522 U.S. at 146. Here, the "analytical gap" between the publications relied upon by SJS and the opinions they have offered is a canyon.

C. SJS's Treatment of the Recently Published Augustine Study Further Underscores Their "Ask No Questions" Approach to Litigation Testimony.

SJS's "ask no questions" approach to the published literature favorable to Plaintiffs is further demonstrated by the embarrassing episode of a recent publication by Dr. Augustine.

In June of this year, Dr. Augustine published an article in an Internet journal, reporting on a "study" at three hospitals. Augustine claimed that the study demonstrated that transitioning from the Bair Hugger system to Augustine's HotDog decreased the risk of joint infections by 78 percent. According to Augustine, his study "shares a study design similar to the McGovern study" and "corroborates the findings of the McGovern study." DX47, Scott D. Augustine, "Forced-air warming discontinued: periprosthetic joint

infection rates drop," 9(2):6998 *Orthop. Rev.* 39, 40-41 (2017). Indeed, everything that Plaintiffs say in defense of the McGovern study they could have said about the Augustine study: It was peer reviewed. It was published. It was "pre-litigation," because it was based on data that mostly predates the filing of the first Bair Hugger case. Its results are "too strong" to be the product of confounders. Its author "stands by" the study. In fact, from Plaintiffs' standpoint, it should be even more reliable than the McGovern study because it finds consistent results across three hospitals, rather than just one, and therefore is less likely to be the result of hospital-specific confounders.

Plaintiffs rushed to embrace Augustine's publication, putting it in the hands of their general causation experts as further "support" for their opinion. Dr. Samet volunteered at his deposition that he is relying on the article, and indeed that Augustine's article provides sufficient foundation by itself for his general-causation opinion. DX25, Samet Dep. at 30:4-35:13 (testifying that he regards Augustine's article as "another piece of observational evidence that provides an estimate of risk of deep joint infection associated with the Bair Hugger device versus the comparison"); 165:13-24 (if McGovern was taken out of consideration, Dr. Samet would point to Augustine's study as support for his opinions). Dr. Jarvis listed the Augustine study on a statement of "Additional Materials Reviewed" that was produced to Defendants at Jarvis's deposition. DX43, Jarvis Dep. at 26:7-13. Jarvis described the Augustine publication as "an additional piece of the puzzle" from a "peer-reviewed journal" supporting his causation opinion. *Id.* at 145:25-147:14 (Jarvis: "And the three different hospitals using what looks like pretty similar methodologies found an increase in prosthetic joint infections when they were using the Bair Hugger."). And

finally, Dr. Stonnington testified that the McGovern study alone was not "conclusive" proof of causation by itself, but that he considered it to be corroborated by Augustine's study. DX26, Stonnington Dep. at 119:13-121:23 (testifying regarding McGovern that "you cannot hang your hat on one study" but that "Augustine has also said the same thing").

In short, Plaintiffs and SJS were aware of the shortcomings of McGovern and decided to rely on Augustine to demonstrate "consistency" across multiple observational studies. And then things fell apart. Defendants sought discovery from the three hospitals discussed in the Augustine study. In responding to Defendants' motion to compel, Ridgeview insisted to this Court that it did not participate in any "study" with Augustine:

> Ridgeview Medical Center did not participate in a study with Scott Augustine or any entity owned by Scott Augustine, including but not limited to, Augustine Temperature Management or Augustine BioMedical Design.
>
> The study never came to fruition between Ridgeview Medical Center and Scott Augustine, or any entity owned in whole or in part by him.

ECF No. 445, Aff. of Julie Hauser at ¶¶ 31-32; *see also* ECF No. 444, Ridgeview Opp. to Mot. to Remove Confidential Designation, at 2. Ridgeview also produced documents in which its own personnel concluded that Ridgeview's reduced infection rates were not caused by its switch to the HotDog. ECF No. 402, Hulse Decl. Ex. D, at 1 ("[T]here is no data to support a direct correlation to [the HotDog patient warming system] and our reduced infection rates.").

Then, just two weeks ago, in response to Defendants' subpoena, South Nassau Communities Hospital produced an affidavit from Dr. Jonathan Singer, the doctor who

provided data to Augustine following his hospital's trial use of the HotDog. Dr. Singer expresses his shock and consternation upon reading Augustine's publication. DX48, Singer Aff. ¶ 9. The errors he identifies include, first, Augustine's statement that South Nassau had used the Bair Hugger system prior to transitioning to the HotDog. It had not used the Bair Hugger system. *Id.* The article also falsely claimed that South Nassau had provided baseline joint infection rates for a one-year period. They had not. *Id.* The article falsely stated that no other significant changes had been made to reduce infections during the time period. South Nassau never provided such information to Augustine. *Id.* And South Nassau never authorized a "study," and did not seek IRB approval as it would have been required to for a real study. *Id.*

In other words, the Augustine study is based on manipulated data. It is junk science.

But when Plaintiffs served up the Augustine study to Samet, Jarvis, and Stonnington, they asked no questions (just as they failed to scrutinize the McGovern study and its underlying data) and declared it to be further, important support for their causation opinions. The Augustine study, they opined, corroborates the McGovern study and shows consistency across observational studies. We don't have to ask questions, they say, because the study was "peer reviewed."

As the facts began to emerge, Plaintiffs disavowed Augustine's publication and represented to the Court that they did not intend to introduce it as evidence at trial. ECF No. 682 at 2. Given this disavowal, the Court need not evaluate Augustine's publication as support for SJS's opinions, even though SJS themselves have never themselves explicitly repudiated it. But the Court *should* consider SJS's unquestioning acceptance of

and reliance on Augustine's publication as powerful evidence of how they have approached their roles as litigation experts. Their approach to the Augustine publication was entirely consistent with their approach to the McGovern study, upon which the admissibility of their testimony depends.

IV. PLAINTIFFS' EXPERTS' CAUSATION THEORY HAS BEEN UNIFORMLY REJECTED BY THE SCIENTIFIC COMMUNITY.

Finally, Plaintiffs do not seriously dispute that SJS's causation theory has been uniformly rejected by independent scientific authorities. This too is a relevant factor for the Court to consider in assessing the admissibility of SJS's opinions. *See* Fed. R. Evid. 702 Adv. Comm. Notes (2000) (noting that "whether the technique or theory has been generally accepted in the scientific community" was one of the non-exclusive factors explicated by the *Daubert* Court).

Independent reviews published by the Association of periOperative Registered Nurses (AORN), the ECRI Institute, the *Journal of Bone & Joint Surgery*, the *Journal of Arthroplasty*, and the Duke Infection Control Outreach Network have all concluded that the scientific literature relied upon by SJS, including the McGovern study, does not demonstrate that the Bair Hugger system increases the risk of surgical site infections. Mem. at 26-28. An assembly of 400 experts in musculoskeletal infection from 52 countries reached a "strong consensus" statement that "no studies have shown an increase in SSI [surgical site infections] related to the use of these devices." *Id.* at 27. And the FDA now has issued a letter, based on its own review of the literature, stating that it has "been unable to identify a consistently reported association between the use of forced air thermal

regulating systems and surgical site infection." DX1, 8/30/2017 FDA Ltr. to Health Care Providers at 1. The FDA "continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems [of which the Bair Hugger is the most widely used]) for surgical procedures when clinically warranted." *Id.*

There can be no doubt that the FDA has considered the McGovern study and the other studies to emerge from Augustine's publication factory. In 2012, the FDA issued a warning letter to Augustine based on "inappropriate claims" made on his website. One of these claims cited the McGovern study ("an article from the November 2011 issue of the Journal of Bone and Joint Surgery") for the proposition that Augustine's HotDog reduces infections as compared to the Bair Hugger system. He apparently submitted the McGovern study and the other studies he and Plaintiffs rely upon to the FDA. DX41, 7/24/2012 FDA Warning Ltr. to Augustine at 2. In response, the FDA concluded that Augustine's evidence did not "provide conclusive evidence of a causal relationship between the use of forced air warming and higher infection rates." DX42, 12/10/2012 FDA Ltr. to Augustine at 1 (highlighting in original produced by Augustine).

This uniform rejection of Plaintiffs' experts' conclusions by independent authorities is an additional factor supporting the exclusion of their testimony from the MDL. Fed. R. Evid. 702. It is even more potent under Minnesota law, which ***requires*** general acceptance for an expert's theory to be admissible. Minn. R. Evid. 702; *McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. App. 2004) (affirming exclusion of expert's general causation theory that was not generally accepted).

CONCLUSION

SJS's causation opinions depend on the reliability of the McGovern study. Without McGovern, they have no scientific basis to opine that use of the Bair Hugger system is even associated with higher infection rates, and have no basis to quantify the increased risk. Yet, despite the vital importance of the McGovern study to their opinions, SJS failed to apply the scientific method to evaluating the study and its limitations, and in reaching causation opinions that go far beyond what McGovern (or any other study) can support. At bottom, their opinions depend on an unsupportable leap of faith, not on any reliable methodology that they might use in their non-litigation work. As such, their opinions should be excluded from the MDL under Fed. R. Evid. 702 and *Daubert*, and from the Ramsey County cases under Minn. R. Evid. 702 and the *Frye-Mack* standard. Their opinions also should be excluded under Minnesota law because they are entirely contrary to the consensus viewpoint of independent medical authorities and the FDA.

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Respectfully submitted,

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